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| 09/937,383      | 09/25/2001  | Mats Malmquist       | MH/AN45888          | 8515             |

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YOUNG & THOMPSON  
745 SOUTH 23RD STREET 2ND FLOOR  
ARLINGTON, VA 22202

EXAMINER

BEISNER, WILLIAM H

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
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1744

DATE MAILED: 09/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/937,383

Applicant(s)

MALMQUIST, MATS

Examiner

William H. Beisner

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Pre. Amds of 9/25/01 and 12/18/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 36-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

2. The information disclosure statement filed 25 Sept. 2001 has been considered and made of record.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 45 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 45 and 59 recite that the device and method of use "simultaneous heating and cooling". This claim language is indefinite because it is not clear if this means that the heater and cooling devices are both provided to be exposed to the vessel and the vessel passes by each during a single rotation to perform the desired temperature cycling or does this mean that the devices are both on and their combined temperatures result in the final desired temperature? Clarification and/or correction is requested.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 36, 42, 44, 46, 50, 56, 58 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Corbett et al.(WO 98/49340).

With respect to claims 36 and 50, the reference of Corbett et al. discloses a device and method of use for performing PCR in a centrifuge device. The reference discloses loading a reaction vessel (3) with a reaction mixture, subjecting the reaction vessel and its contents to a centrifugal force and heating and/or cooling the reaction mixture in the vessel under the centrifugal force (See page 6, line 26, to page 7, line 3). This method is performed in a means for holding a reaction vessel (3), means for subjecting the vessel to centrifugal force (4) and means for heating and/or cooling the reaction vessel (8,9). With respect to the claimed homogeneous mixture and temperature distribution, in the absence of further positively recited structure and/or method steps within the claims, the system of the primary reference is considered to inherently provide these homogeneous conditions since the vessel is centrifuged and exposed to a gravitational field and the reagents would be the same since the same method, PCR, is performed in the system.

With respect to claims 42 and 56, the reaction vessel is rotated in an environment containing ambient air.

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With respect to claims 44 and 58, the disclosed method includes a cyclic temperature changes (See page 7, line 1).

With respect to claims 46 and 60, the reaction is a PCR reaction.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 37-41, 46-49, 51-55 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corbett et al. (WO 98/49340).

The reference of Corbett et al. has been discussed above.

With respect to claims 37-40 and 51-54, while the reference of Corbett et al. is silent as to the specific amount of centrifugal force the vessel is exposed to, in the absence of a showing of criticality and/or unexpected results, it would have been well within the purview of the skilled

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artisan to determine the optimal amount of centrifugal force based on considerations such as the size of the reaction vessels and properties of the reaction fluids while maintaining reaction condition required to efficiently perform the PCR procedure.

With respect to claims 41 and 55, while the preferred means for heating of the primary reference are convection devices (See page 3, lines 3-4), the reference also discloses that it is known to employ infrared light and microwave sources (See page 3, lines 1-3). As a result, it would have been obvious to one of ordinary skill in the art to employ any of the known means for heating the vessel while creating temperature conditions for efficiently performing PCR.

With respect to claims 47 and 48, while the primary reference is silent as to the temperature the air is heated to, it would have been obvious to one of ordinary skill in the art to determine the optimal temperature to heat the air based on considerations such as the volume of the chamber and/or volume of the reaction solutions that need to be heated.

With respect to claim 49, while the primary reference is silent as to the length of time for the PCR to be performed, it would have been obvious to one of ordinary skill in the art to determine the length of time to perform the amplification procedure based merely on the number of amplifications to be performed.

With respect to claims 46 and 59, it would have been obvious to one of ordinary skill in the art to simultaneously employ both the heater and cooling system so as to produce a desired temperature which the chamber of the device.

10. Claims 43 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corbett et al. (WO 98/49340) in view of Hieb et al. (US 5,232,667).

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The reference of Corbett et al. has been discussed above.

While the reference of Corbett et al. discloses the use of a temperature sensor for controlling the PCR process, the reference does not disclose the use of an IR-sensor as recited in the instant claims.

The reference of Hieb et al. discloses that it is known in the art to employ IR-sensor probes for monitoring the temperature within a sample chamber (See column 2, lines 24-28).

In view of this teaching, it would have been obvious to employ the IR-sensor of the reference of Hieb et al. as a temperature sensor in the system of the primary reference for the known and expected result of providing an alternative means recognized in the art to achieve the same result, monitoring the temperature within a sample chamber. The IR-sensor is desirable because of its art recognized speed and accuracy.

### ***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

  
William H. Beisner

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Primary Examiner  
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WHB